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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/069,755 | 02/28/2002 | Yoshimitsu Iida | IIDA=20 | 3713 |
| 1444 | 7590 | 07/20/2004 | EXAMINER | |
| BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303 | | | WEBMAN, EDWARD J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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| ART UNIT | PAPER NUMBER |
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6/27/04

DATE MAILED:

This is a communication from the examiner in charge of your application.
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OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 5/18/04

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1, 2, 4-17 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 2, 4-17 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1617

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6, 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 3264532 (JP'532) in view of US 4693892 (US '892) JP 4046122 (JP '122) JP 63215641 (JP '641) and US '394.

JP '532 teaches soft capsules containing an active vitamin D.

US '892 teaches capsules which have an outstanding light protection effect (column 2 lines 23-24). Soft capsules comprising titanium dioxide and red or yellow iron oxide are disclosed (examples 6, 7). 0.06-0.5% iron oxide (column 1 line 47) and 0.2-2.0% titanium oxide (column 2 line 27) are disclosed.

It would have been obvious to one of ordinary skill to use the soft capsule of US '892 as the soft capsule for JP '532 for the beneficial effect of its property of protection from light. As to the claimed triglyceride, JP '122 teaches such as a carrier for vitamin D in soft capsules. As to the claimed caramel, JP '641 teaches such for light shielding in soft capsules. 0.01-5% is disclosed. It would have been obvious to one of ordinary skill to add caramel to the soft capsule of JP '532 for its beneficial effect as additional light shielding in view of JP '641 and to use a fatty acid glyceride in JP '532 for its beneficial effect as a carrier for vitamin D in view of JP '122. As to the claimed capsule thickness, such is well-known in the art in view of US '394 (column 9, example 16).

Claims 2-7, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 55141242 (JP '242), US '892 JP '641 and US '394.

JP '532 is described in the first 103.

JP '242 teaches titanium dioxide and caramel in capsules for safe coloring (abstract). 0.01-0.1% titanium oxide and 0.1-3% caramel is disclosed.

It would have been obvious to one of ordinary skill to use titanium dioxide and caramel in the soft capsule of JP '532 for the beneficial effect of providing safe coloring in view of JP '242. As to the claimed soft capsule, US '892 and JP '641, both described in the first 103, teach the use of titanium dioxide and caramel respectively in soft capsules. The statement regarding capsule thickness in the first 103 is incorporated herein.

Claims 1, 4-6, 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '532 in view of JP 4046122 (JP '122), JP '641, '892 and US '394.

JP '532 is discussed in the first 103.

JP '122 teach activated vitamin D in Fatty acid triglyceride in a capsule containing red iron oxide and an opacifier such as titanium white to maintain stability of the vitamin (abstract).

It would have been obvious to one of ordinary skill to use the soft capsule composition of JP '122 as the vehicle for JP '532 to achieve the beneficial effect of stability of the vitamin.

As to the use of red iron oxide and titanium dioxide in soft capsules, US '892, described in the first 103, teaches such. ^{At} 0.06-0.5% and 0.2-2% respectively.

As to the claimed caramel, JP '641 described in the first 103, teaches such at 0.01-5% for light shielding in soft capsules.

It would have been obvious to one of ordinary skill to add caramel to the soft capsule of JP '532 for its beneficial effect of providing additional light shielding in view of JP '641. The statement regarding capsule thickness in the first 103 is incorporated herein.

Applicants argue that JP '532 doesn't teach capsule materials. However, the obvious combinations provide such. Applicants continue to argue that US '892 and JP '641 are limited to a beta carotene and amino acids respectively, however, applicants do not exclude such. Applicants argue that JP '122 teaches hard ^{capsules} ~~applicants~~ rather than soft capsules, however, US '892 indicates that the ingredients recited in JP '122 are usable in soft capsules as well.

No claims allowed.

Any inquiry concerning this communication should be directed to Edward J. Webman at telephone number 571-272-0633.

Webman/tgd

June 30, 2004

